## <u>CLAIMS</u>

## WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising as an active ingredient at least one olanzapine polymorph selected from Form III olanzapine, Form IV olanzapine, Form V olanzapine, and salts and mixtures thereof; and

one or more pharmaceutically acceptable carriers, excipients or diluents;

wherein Forms III, IV and V olanzapine are olanzapine polymorphs having typical x-ray powder diffraction patterns represented by the following interplanar spacings:

| FORM-III      | FORM-IV       | FORM IV       |
|---------------|---------------|---------------|
| d-spacing (Å) | d-spacing (Å) | d-spacing (Å) |
| 10.3156       | 9.9487        | 10.5932       |
| 7.1713        | 8.5074        | 10.2170       |
| 6.5014        | 8.2103        | 9.9503        |
| 5.5165        | 4.8172        | 8.5259        |
| 4.8541        | 4.7114        | 7.1016        |
| 4.5578        | 4.6122        | 6.0731        |
| 4.4938        | 4.5282        | 5.2041        |
| 4.4536        | 4.2340        | 4.9856        |
| 4.2588        | 4.0901        | 4.8153        |
| 3.9898        | 3.7574        | 4.7514        |
| 3.7288        | 3.6989        | 4.5302        |
| 3.5626        |               | 4.4714        |
| 3.0262        |               | 4.2271        |
|               |               | 4.1307        |
|               |               | 3.9880        |
|               |               | 3.7763        |
|               |               | 3.7167        |
|               |               | 3.5315.       |

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- 2. The pharmaceutical composition according to claim 1, wherein the olanzapine polymorph is Form III olanzapine.
- 3. The pharmaceutical composition according to claim 2, wherein the Form III olanzapine is further characterized by substantially the following x-ray powder diffraction pattern, wherein d represents the interplanar spacing and  $I/I_1$  represents the typical relative intensities:

| d-spacing (Å) | $I/I_1$ |
|---------------|---------|
| 10.3156       | 100     |
| 7.1713        | 16      |
| 6.5014        | 17      |
| 5.5165        | 24      |
| 4.8541        | 46      |
| 4.5578        | 24      |
| 4.4938        | 38      |
| 4.4536        | 36      |
| 4.2588        | 49      |
| 3.9898        | 52      |
| 3.7288        | 42      |
| 3.5626        | 25      |
| 3.0262        | 18.     |

4. The pharmaceutical composition according to claim 2, wherein the Form III olanzapine is further characterized by having an infrared spectrum having absorbances at the following wavenumbers:

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- 5. The pharmaceutical composition according to claim 1, wherein the olanzapine polymorph is Form IV olanzapine.
- 6. The pharmaceutical composition according to claim 5, wherein the Form IV olanzapine is further characterized by substantially the following x-ray powder diffraction pattern, wherein d represents the interplanar spacing and I/I<sub>1</sub> represents the typical relative intensities:

| d-spacing (Å) | $I/I_1$ |
|---------------|---------|
| 9.9487        | 83      |
| 8.5074        | 15      |
| 8.2103        | 17      |
| 4.8172        | 100     |
| 4.7114        | 41      |
| 4.6122        | 35      |
| 4.5282        | 33      |
| 4.2340        | 29      |
| 4.0901        | 32      |
| 3.7574        | 23      |
| 3.6989        | 40.     |

7. The pharmaceutical composition according to claim 5, wherein the Form IV olanzapine is further characterized by having an infrared spectrum having absorbances at the following wavenumbers:

- 8. The pharmaceutical composition according to claim 1, wherein the olanzapine polymorph is Form V olanzapine.
- 9. The pharmaceutical composition according to claim 8, wherein the Form V olanzapine is further characterized by substantially the following x-ray powder diffraction pattern, wherein d represents the interplanar spacing and  $I/I_1$  represents the typical relative intensities:

| d-spacing (Á) | $I/I_1$ |
|---------------|---------|
| 10.5932       | 17      |
| 10.2170       | 100     |
| 9.9503        | 57      |
| 8.5259        | 22      |
| 7.1016        | 17      |
| 6.0731        | 17      |
| 5.2041        | 19      |
| 4.9856        | 20      |
| 4.8153        | 62      |
| 4.7514        | 34      |
| 4.5302        | 24      |
| 4.4714        | 51      |
| 4.2271        | 91      |
| 4.1307        | 40      |
| 3.9880        | 31      |
| 3.7763        | 10      |
| 3.7167        | 62      |
| 3.5315        | 22.     |

10. The pharmaceutical composition according to claim 8, wherein the Form V olanzapine is further characterized by having an infrared spectrum having absorbances at the following wavenumbers:

11. A pharmaceutical composition containing as an active ingredient at least one olanzapine polymorph selected from Form III olanzapine, Form IV olanzapine, Form V olanzapine, and salts and mixtures thereof;

wherein Forms III, IV and V olanzapine are olanzapine polymorphs having typical x-ray powder diffraction patterns represented by the following interplanar spacings:

| FORM-III      | FORM-IV       | FORM IV       |
|---------------|---------------|---------------|
| d-spacing (Å) | d-spacing (Å) | d-spacing (Å) |
| 10.3156       | 9.9487        | 10.5932       |
| 7.1713        | 8.5074        | 10.2170       |
| 6.5014        | 8.2103        | 9.9503        |
| 5.5165        | 4.8172        | 8.5259        |
| 4.8541        | 4.7114        | 7.1016        |
| 4.5578        | 4.6122        | 6.0731        |
| 4.4938        | 4.5282        | 5.2041        |
| 4.4536        | 4.2340        | 4.9856        |
| 4.2588        | 4.0901        | 4.8153        |
| 3.9898        | 3.7574        | 4.7514        |
| 3.7288        | 3.6989        | 4.5302        |
| 3.5626        |               | 4.4714        |
| 3.0262        |               | 4.2271        |
|               |               | 4.1307        |

| 3.9880  |
|---------|
| 3.7763  |
| 3.7167  |
| 3.5315. |

12. A method of treating a patient having a psychotic condition, mild anxiety or gastrointestinal condition comprising administering a therapeutically effective amount of at least one olanzapine polymorph to said patient;

wherein the at least one olanzapine polymorph is selected from Form III olanzapine, Form IV olanzapine, Form V olanzapine, and salts and mixtures thereof; and

wherein Forms III, IV and V olanzapine are olanzapine polymorphs having typical x-ray powder diffraction patterns represented by the following interplanar spacings:

| FORM-III      | FORM-IV       | FORM IV       |
|---------------|---------------|---------------|
| d-spacing (Å) | d-spacing (Å) | d-spacing (Å) |
| 10.3156       | 9.9487        | 10.5932       |
| 7.1713        | 8.5074        | 10.2170       |
| 6.5014        | 8.2103        | 9.9503        |
| 5.5165        | 4.8172        | 8.5259        |
| 4.8541        | 4.7114        | 7.1016        |
| 4.5578        | 4.6122        | 6.0731        |
| 4.4938        | 4.5282        | 5.2041        |
| 4.4536        | 4.2340        | 4.9856        |
| 4.2588        | 4.0901        | 4.8153        |
| 3.9898        | 3.7574        | 4.7514        |
| 3.7288        | 3.6989        | 4.5302        |
| 3.5626        |               | 4.4714        |
| 3.0262        |               | 4.2271        |
|               |               | 4.1307        |
|               |               | 3.9880        |
|               |               | 3.7763        |

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|  | 3.7167  |
|--|---------|
|  | 3.5315. |

- 13. The method according to claim 12, wherein the olanzapine polymorph is Form III olanzapine.
- 14. The method according to claim 12, wherein the olanzapine polymorph is Form IV olanzapine.
- 15. The method according to claim 12, wherein the olanzapine polymorph is Form V olanzapine.
- 16. A method of treating a patient having a psychotic condition selected from schizophrenia and related disorders, acute mania, Bipolar I Disorder, psychotic mood disorder and psychosis associated with Alzheimer's disease comprising administering a therapeutically effective amount of at least one olanzapine polymorph to said patient;

wherein the at least one olanzapine polymorph is selected from Form III olanzapine, Form IV olanzapine, Form V olanzapine, and salts and mixtures thereof; and

wherein Forms III, IV and V olanzapine are olanzapine polymorphs having typical x-ray powder diffraction patterns represented by the following interplanar spacings:

| FORM-III      | FORM-IV       | FORM IV       |
|---------------|---------------|---------------|
| d-spacing (Å) | d-spacing (Å) | d-spacing (Å) |
| 10.3156       | 9.9487        | 10.5932       |
| 7.1713        | 8.5074        | 10.2170       |
| 6.5014        | 8.2103        | 9.9503        |
| 5.5165        | 4.8172        | 8.5259        |
| 4.8541        | 4.7114        | 7.1016        |
| 4.5578        | 4.6122        | 6.0731        |
| 4.4938        | 4.5282        | 5.2041        |

| 4.4536 | 4.2340 | 4.9856  |
|--------|--------|---------|
| 4.2588 | 4.0901 | 4.8153  |
| 3.9898 | 3.7574 | 4.7514  |
| 3.7288 | 3.6989 | 4.5302  |
| 3.5626 |        | 4.4714  |
| 3.0262 |        | 4.2271  |
|        |        | 4.1307  |
|        |        | 3.9880  |
|        |        | 3.7763  |
|        |        | 3.7167  |
|        |        | 3.5315. |

- 17. The method according to claim 16, wherein the olanzapine polymorph is Form III olanzapine.
- 18. The method according to claim 16, wherein the olanzapine polymorph is Form IV olanzapine.
- 19. The method according to claim 16, wherein the olanzapine polymorph is Form V olanzapine.